PANIPAT INSTITUTE OF ENGINEERING AND TECHNOLOGY, PANIPAT

DEPARTMENT OF PHARMACY

Course: B. Pharmacy

LESSON PLAN

Faculty Name: Dr. Daisy Arora **Class: B. Pharmacy- 6th semester**

Subject: Biopharmaceutics and Pharmacokinetics **Subject Code: BP 604T**

Scope: This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.

Aim and Objective:

- To understand the basics of Biopharmaceutics & Pharmacokinetics.
- To understand the kinetics of drug absorption using different kinetic models.
- To know the kinetics of distribution of the drug administration.
- To understand the kinetics of dose clearance after drug administration.
- To understand the mechanistic aspect of metabolism and hepatic clearance.
- To know about non linear pharmacokinetics.
- To understand about bioavailability and bioequivalence study.

Course outcome: At completion of this course it is expected that students will be able to –

- Define the basic concepts in biopharmaceutics and pharmacokinetics.
- Use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- Critically evaluate biopharmaceutic studies involving drug product equivalency
- Design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- Detect potential clinical pharmacokinetic problems and apply basic pharmacokinetic principles to solve them

Number of Lesson: 50 Each lecture: 01 hours

Chapter	Lesson No.	Particular	Remark/Date
Module 1: Biopharmaceutics	1.	Introduction: Basic concepts of Biopharmaceutics and Pharmacokinetics	
	2.	Their role in formulation development and clinical setting.	
	3.	Biopharmaceutics : a. Passage of drugs across biological barrier (passive diffusion, active transport, facilitated diffusion and pinocytosis)	
	4.	Active transport, Facilitated diffusion and pinocytosis	
	5.	Physicochemical factors influencing absorption	
	6.	Physicochemical factors influencing absorption	
	7.	Pharmaceutical factors influencing absorption	
	8.	Drug distribution in the body, Plasma protein binding: significance	
	9.	Plasma protein binding: factors influencing	
	10.	Plasma protein binding: kinetics	
Module- 03 One Compartment modeling	11.	Significance of plasma drug concentration measurement	
	12.	Compartment and model-Definition and Scope.	
	13.	Pharmacokinetics of drug absorption – Zero order and absorption rate constant	
	14.	Pharmacokinetics of drug absorption first order	
	15.	Compartment kinetics- one compartment models.	
	16.	Determination of pharmacokinetic parameters from plasma data after drug administration by intravascular route.	
	17.	Determination of pharmacokinetic parameters from plasma data after drug administration by oral route.	
	18.	Numerical problems	
	19.	Volume of distribution and distribution coefficient	
	20.	Curve fitting (method of Residuals), regression procedures.	
	21.	Wagner – Nelson Method	
	22.	Determination of pharmacokinetic parameters from urine data after drug administration by intravascular route.	
	23.	Determination of pharmacokinetic parameters from urine data after drug administration by oral route.	
	24.	Non-Compartmental concept of mean residence time (MRT) Significance & applications	
Module- 04 Compartment	25.	Compartment kinetics- two compartment models.	
	26.	Loo- Reigelman method	

kinetics- two compartment models.	27.	Kinetics of multiple dosing, steady state drug levels,	
	28.	calculation of loading and mainetnance doses and their significance in clinical setting	
	29.	Numerical problems	
	30.	Numerical problems	
Module- 02	31.	Drug metabolism and basic understanding metabolic pathways renal excretion of drugs,	
	32.	Clearance concept,	
	33.	Mechanism of renal clearance, clearance ratio, Determination of renal clearance.	
	34.	Extraction ratio, Hepatic clearance, biliary excretion, Extrahepatic circulation.	
	35.	Definitions, objectives	
	36.	Measures of bioavailability, Cmax, tmax and area under the curve (AUC)	
	37.	Bioequivalence	
	38.	Design of single dose bioequivalence study Relevant statistics	
	39.	Review of regulatory requirements for conduct of bioequivalent studies.	
	40.	Review of regulatory requirements for conduct of bioequivalent studies.	
Module- 05 Non-linear pharmacokinetics	41.	Nonlinear Pharmacokinetics: a. Introduction	
	42.	b. Factors causing Non-linearity	
	43.	Significance, principle of superposition,	
	44.	Michaelis Menten Equation,	
	45.	Detection of non-linearity (Saturation mechanism).	
	46.	Significance	
	47.	Revision and discussion of old question papers	
	48.	Revision and discussion of old question papers	
	49.	Revision and discussion of old question papers	
	50.	Revision and discussion of old question papers	

Teacher in-charge **Academic Incharge** **Principal**